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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1643

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,835

Applicant(s)

MULTHOFF, GABRIELE

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49,61-77 and 83-87 is/are pending in the application.
- 4a) Of the above claim(s) 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-77 and 83-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: MULTHOFF, GABRIELE

1. The amendment filed 3/03/2006 is acknowledged and entered into the record. Accordingly, claims 1-48, 50-60, and 78-82 are canceled without prejudice or disclaimer.
2. Claims 49, 61-77, and 83-87 are pending, claim 49 is withdrawn from further consideration as being drawn to non-elected subject matter.
3. Claims 61-77 and 83-87 are examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn - 35 U.S.C. § 112, 2nd paragraph

5. The rejection of claims 64-65 and 69 under 35 USC § 112, 2nd paragraph as being vague and indefinite is withdrawn in view of the persuasive arguments set forth by the applicant in the paper filed 3/3/2006.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

6. The rejection of claims 61-77 and 83-87 under 35 USC § 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the claims of the instant application are supported by adequate written description. Specifically, applicant argues that a protein of at least 70% homology to amino acids 384-641 of SEQ ID No: 1 has been used. Applicant indicates that the protein rHsp70homC (herein HSP70-Hom) shares 94% identity to amino acids 384-561 and shares 84% homology to amino acids

384-641 of SEQ ID No: 1. Applicant additionally indicates that the specification on page 15 teaches the actual reduction to practice of a sequence that falls within the claimed sequence homology range (i.e. the use of HSP70-Hom). Applicant additionally contends that the art teaches sequences/ proteins that are at least 70% homologous to amino acids 384-641 of SEQ ID No: 1. In support of this contention, applicant cites Milnet and Campbell (which teaches Hsp70-Hom and Hsp70-B both of which are at least 70% homologous to amino acids 384-641) and Multhoff *et al* (which provides an overview of the Hsp70 multigene family). Applicant concludes by indicating that the art provides “a vast source of the genus of Hsp70 sequences that are encompassed by the claimed method.” Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

In deciding *The Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (CAFC 1997), the Federal Circuit held that a generic statement that defines a genus of nucleic acids *by only their functional activity* does not provide an adequate written description of the genus. By analogy, a generic statement that defines a genus of polypeptides having 70% or greater homology to amino acids 384-641 of SEQ ID No: 1 by only their common ability to induce an immune response by NK cells, wherein the response increases cytolytic activity of the NK cells or stimulates NK cell proliferation does not serve to adequately describe the genus as whole. The Court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the structure,

formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members.

“[G]eneralized language may not suffice if it does not convey the detailed identity of an invention.” *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). Furthermore, the Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568). In this instance, as in that, there is no language that adequately describes with the requisite degree of particularity necessary to satisfy the written description requirement the genus of structurally variable polypeptides that is at least 70% homologous to amino acids 384-641 wherein the polypeptide is capable of inducing an immune response by NK cells as specifically claimed. Although applicants have pointed to several species of HSPs that may fall within the genus of at least 70% homologous to amino acids 384-641 of SEQ ID No: 1, as indicated by the Courts, the claimed genus is unpredictable with regards to those species that have not been specifically enumerated. Specifically, the claims encompass polypeptide variants that are at least 70% identical to amino acids 384-641 of SEQ ID No: 1. Neither the

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specification nor the art of record have specifically indicated which portions of the polypeptide within amino acids of 384-641 of SEQ ID No: 1 are required for the claimed function. Moreover, the claims encompass variants of polypeptides comprising amino acids 384-641 of SEQ ID No: 1 and the specification has not provided any guidance on what sequences or amino acids substitutions could be made or modified without affecting the polypeptides ability to induce an immune response by NK cells as claimed. Again, a description of what a material does, rather than of what it is, does not suffice to describe the claimed invention.

Applicant further argues even assuming *arguendo*, that one of skill in the art did not want to rely on the teachings provided in the art, the specification as filed provided sufficient guidance on how to make and test appropriate derivatives of the exemplified Hsp70 protein and fragments thereof (applicant points to pages 3-5 and example 1 of the specification. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). *See Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Moreover, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. In the instant case, a method of making and screening for polypeptides that are at least 70% homologous to amino acids 384-641 of SEQ ID No: 1 does not provide specific information regarding the specific structure or function or a known correlation between structure and function. It essentially provides for a starting point for those of skill in the art to experiment and look for those structural variants. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Applicants have not shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; and Applicant has not described distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention at the time the application was filed.

Applicant continues to argue by referring to the Written Description Guidelines example 14. Applicant indicates that the facts of the instant case are analogous to those presented in example 14 because members of the genus claimed do not significantly vary because all sequence must be at least 70% homologous to amino acids 384-641 of SEQ ID No: 1 and further must possess the activity of inducing an immune response by NK cells. Applicant also indicates that "SEQ ID No: 1 is a representative species for the genus since all polypeptides must have at least 70% homology to this sequence." Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

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Example 14, as alluded to by the applicant, discusses sequence variants that are at least 95% or great in identity to a reference sequence. The sequences encompassed by the limitation of 95% or greater was deemed not to differ or vary significantly also it was coupled with a known function of catalyzing a reaction of A to B. In the instant case, the sequences encompassed by the limitation of at least 70% identity is a much broader in scope and include sequences that have yet to be disclosed and further not specifically identified by either the applicant and those of skill in the art. Moreover, the function claimed in the instant case, is not a specific function of the protein, but rather a characteristic of the peptide or any peptide, because any peptide when administered in vitro or in vivo would have such a function and therefore applies generally to any peptide fragment. As indicated above, neither the specification nor the prior art teaches which portions within amino acids 384-641 of SEQ ID No: 1 is critical for the induction of an immune response by NK cells. As such, given the limited disclosure regarding the genus of polypeptides claimed, the applicant's disclosure is deficient in written description.

Therefore, the rejection of claims under 35 USC 112, 1st paragraph as lacking adequate written description is maintained for the reasons of record.

Conclusion

No claim is allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
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March 23, 2006


CHRISTOPHER YAEN
PATENT EXAMINER